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EXAMINER

DAVIS, MINH TAM B

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

***DETAILED ACTION***

**Claims 1-3, 5-8, 16-18, 21-23 are examined in the instant application.**

***Withdrawn Rejection***

The 112, first paragraph, new matter has been withdrawn in view of the amendment.

***Claim Rejections - 35 USC § 112, First Paragraph, Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-8, 16-18, 21-23 remain rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for a method for diagnosing GPC3 protein expressing cancer, including hepatic cancer, for reasons already of record on paper of 2/25/10.

The response asserts as follows:

Claim 1 has been amended without prejudice to recite in relevant part: "A diagnostic method for GPC3 protein expressing cancer, said method comprising detecting a soluble GPC3 protein level in a test sample selected from the group consisting of blood, serum and plasma, and determining whether said detected soluble GPC3 level in the test sample is greater than a control level of GPC3 in normal non-cancerous blood, serum or plasma."

Applicants respectfully direct the Examiner's attention to the definition of "diagnosis" and "diagnostic" as found in "Churchill's Medical Dictionary", a copy of the relevant portion is attached herewith as Exhibit A, which recites in relevant parts:

diagnosis: "1. A determination of the nature or identity of a disease, typically based on an analysis of signs and symptoms, the patient's medical history, and often on the results of laboratory tests."

Diagnostic: "2. Contributing to or useful in the process of reaching a diagnosis."

Applicant note that the recitation of the term "diagnosis" as found in "Churchill's Medical Dictionary", a copy of the relevant portion is attached herewith as Exhibit A, further states in relevant part: "The use of laboratory findings to establish a diagnosis without reference to the subject's history or physical findings."

Therefore the claim is enabled because a person of ordinary skill in the art would be able to measure the GPC3 in a test sample, and determine whether a test sample (blood, serum, or plasma) contains "greater levels" of GPC3 than the levels of GPC3 found in a normal control, and thereby be enabled to use said results for a diagnostic method for GPC3 protein expressing cancer. Support for the foregoing may be found in paragraph [0007] of U.S. Patent Publication No. 2006/0014223 of the present specification which recites: "The expression of GPC3 protein has also been detected in cancer cell lines other than hepatic cancer cell lines, such as lung cancer, colon cancer, mammary cancer, prostate cancer, pancreatic cancer, and lymphomas. Hence, GPC3 may possibly be applied to the diagnosis of hepatic cancer as well as many other cancers."

Applicants respectfully submit that one of ordinary skill can determine whether a test sample (blood, serum, or plasma) contains "greater levels" of GPC3 than the levels of GPC3 found in a normal control, and thereby use the results to diagnose GPC3 protein expressing cancer, as disclosed in the subject application.

The response has been considered but is not found to be persuasive for the following reasons:

The claims are reasonably interpreted as a method for **detecting** a genus of cancers that overexpress GPC3 protein, including hepatic cancer, that has an increased in the level of GPC3 in blood, serum or plasma, as compared to that of non-cancerous blood, serum or plasma, and would not be **limited** to a method for "contributing or useful in the process of reaching a diagnosis" of GPC3 protein expressing cancer, including hepatic cancer.

Other than a single cancer, melanoma, one cannot predict the claimed method would be successful in detecting the presence of any cancer that overexpresses GPC3, including hepatic cancer, when based on an increase in the level of GPC3 in blood, serum or plasma as compared to that of healthy individuals for the following reasons:

1) The claimed method is **non-specific for hepatic cancer**, and cannot distinguish suspected hepatic cancer from liver cirrhosis, because the level of soluble GPC3 in blood or serum or plasma is increased in both hepatic cancer patient and liver cirrhosis as compared to soluble GPC3 in blood or serum or plasma of healthy individual, in view of the teaching of Hippo et al, of record.

2) Other than a **single** cancer, melanoma, that can be detected with the claimed method, one cannot predict there exist any other cancers that overexpress the protein GPC3 in blood,

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serum or plasma. One cannot predict whether cancers such as lung cancer, colon cancer, mammary cancer, prostate cancer, and lymphomas overexpress the protein GPC3 in blood, serum or plasma, when based solely on the data from cancer cell lines in culture, due to the well known cell culture artifacts, in view of the teaching of Drexler et al, Tian et al, Van Dyke et al, and Kunkel et al, all of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS

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March 30, 2010

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643